DeviceSafety

Alarming monitor error

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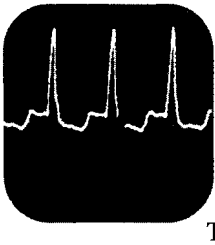
A 67-YEAR-OLD MAN with a history of schwannoma tumors, hypertension, heart failure, hypertensive cardiomyopathy, and hyperlipidemia was admitted to the ICU in serious condition. He developed a cardiac arrhythmia — ventricular tachycardia that progressed to ventricular fibrillation — but his bedside monitor never produced a "lethal-arrhythmia" alarm or printout. Several minutes elapsed before someone called a code, and the patient died.

What went wrong?



The alarm never sounded because it wasn't turned on in the first place. According to the hospital's biomedical department, the alarm suspension log revealed that all alarms for this patient were turned off before he developed the arrhythmia. The manufacturer investigated and concluded that the device was performing to specifications and hadn't failed mechanically.

What precautions can you take?

Alarm modes vary according to the type of monitoring system, so become completely familiar with the ones you use.

- Establish and maintain a working knowledge of all alarm settings for the telemetry and bedside monitoring systems used at your facility.
- Check the alarm system settings for each monitored patient at the beginning and end of each shift. Also check the settings before and after a patient is switched to a portable monitor (for example, when he leaves the unit for a procedure).
- Promptly notify the proper person (such as someone in your facility's biomedical department) if a monitor malfunctions or fails in any way. N

For more information a telemetry and b3 side monitors reported to the FDA. please contact the author at BXG@CDRH.FDA.GOV.

Although yc ed to support the adverse event–reporting policy of your health care facility you may voluntarily report a medical device that doesn't per as intended by alling MedWatch at 1-80(-FDA-1088 (fax: 1-800-FDA-0178 The opinions and statements in this report are those of the author and may not reflect the views of the Department of Health and Human Services. Device Safety is coordinated by Beverly Gallauresi, RN. MPH, BS.